

DRUGS AND DEVICES ACTIONABLE BECAUSE OF FALSE AND MISLEADING CLAIMS

DRUGS FOR HUMAN USE*

2578. Misbranding of Kaadt Diabetic Treatment. U. S. v. Dr. Charles F. Kaadt (Kaadt Diabetic Institute and Kaadt Diabetic Clinic), Dr. Peter S. Kaadt, and Robert S. Benson. Pleas of not guilty. Tried to the jury. Verdict of guilty. Doctors Charles F. Kaadt and Peter S. Kaadt each sentenced to pay fine of \$1,000 and costs and to serve 1 year in prison on each of the seven counts of the indictment, with the sentences on first three counts to run consecutively, those on remaining counts to be suspended, and defendants to be placed on probation when released from prison. Defendant Benson sentenced to pay fine of \$350 and to serve one year in prison, with prison sentence to be suspended and defendant to be placed on probation for two years. Judgment affirmed upon appeal. (F. D. C. No. 21454. Sample Nos. 23351-H to 23353-H, incl., 51231-H, 51234-H, 54605-H, 54606-H, 70101-H to 70105-H, incl.)

INDICTMENT RETURNED: On or about January 31, 1948, Northern District of Indiana, against Dr. Charles F. Kaadt, trading as the Kaadt Diabetic Institute and Kaadt Diabetic Clinic, South Whitley, Ind., and against Dr. Peter S. Kaadt, who was associated in the conduct of the business of the institute and clinic, and Robert S. Benson, superintendent.

ALLEGED SHIPMENT: Between February 13, 1945, and March 29, 1946, from the State of Indiana into the States of Missouri, Michigan, Minnesota, and Florida.

PRODUCT: The *Kaadt Diabetic Treatment* consisted of a liquid medicine composed essentially of vinegar, potassium nitrate, protein, and a digestant, and adjunctive medication included pepsin, pancreatin, diastase, a laxative drug, and a solution used to test urine for sugar. The treatment was accompanied by certain labeling, consisting of a booklet designated "Of Great Interest to Diabetics," a leaflet entitled "We do Not prescribe any Set diet," and a form letter addressed to "Dear Friend."

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in the accompanying labeling of the *Kaadt Diabetic Treatment* were false and misleading. These statements represented and suggested that the product would be efficacious in the cure, mitigation, and treatment of diabetes, whereas it would not be efficacious for such purposes.

DISPOSITION: On February 27, 1948, a motion for dismissal was filed on behalf of the defendants, on the grounds that the indictment did not state facts sufficient to constitute an offense against the United States, and a similar motion was filed on behalf of Dr. Charles Kaadt, on the grounds that the issue as to the efficacy of the treatment was res judicata. In addition, a motion for a bill of particulars was filed. On February 29, 1948, the motions for dismissal were denied. The motion for a bill of particulars was denied also, except for that part requesting information as to how the circulars and leaflets described in count 3 accompanied the treatment. The defendants thereafter entered a plea of not guilty. The case came on for trial before a jury, at the conclusion of which the jury returned a verdict of guilty. Motions for a new trial and arrested judgment were filed on behalf of the defendants and were subsequently

*See also Nos. 2552-2555, 2559, 2560, 2566, 2570-2577.

denied. On May 4, 1948, the court sentenced Doctors Charles F. Kaadt and Peter S. Kaadt, each to pay a fine of \$1,000 and costs and to serve one year in prison on each of the seven counts of the indictment, with the sentences on the first 3 counts to run consecutively, those on the remaining counts to be suspended, and the defendants to be placed on probation when released from prison. Defendant Robert S. Benson was sentenced to pay a fine of \$350 and to serve one year in prison, with the prison sentence to be suspended and the defendant to be placed on probation for two years, conditioned that he refrain from engaging in a similar business.

An appeal was taken by Doctors Charles F. Kaadt and Peter S. Kaadt to the United States Court of Appeals for the Seventh Circuit, and on December 7, 1948, the following opinion was handed down by that court:

KERNER, *Circuit Judge*: "These are appeals from a judgment sentencing each appellant to a term of imprisonment after a jury had found them guilty as charged in an indictment containing seven counts and alleging violation of the Federal Food, Drug, and Cosmetic Act of June 25, 1938, 52 Stat. 1040, 21 U. S. C. A. § 301 et seq. in that they introduced or delivered for introduction into interstate commerce misbranded drugs.

"Each of the seven counts charged that appellants did, on a date stated, cause to be introduced and delivered for introduction into interstate commerce, consigned to a named individual, an article of drug; that accompanying the drug was certain printed matter; that the statements in the accompanying printed matter were false and misleading because they represented and suggested and created in the mind of the reader the impression that the drug would be efficacious in the cure, mitigation, and treatment of diabetes, whereas in fact and in truth the drug would not be so efficacious.

"The printed matter consisted of (1) a letter signed by C. F. Kaadt, referring to a booklet dealing with his theory of the cause, symptoms, and effect of diabetes and the treatment of same, in which he states: 'I have treated many cases that have been in a very advanced stage * * *. * * I will be pleased to see you'; (2) a leaflet beginning with the words 'We do Not prescribe any Set diet', and (3) a circular entitled 'Of Great Interest to Diabetics.'

"Section 331 (a) of the Act prohibits the introduction into interstate commerce of any drug that is adulterated or misbranded. It is misbranded according to § 352 (a) if its 'labeling is false or misleading in any particular.' The term labeling is defined in § 321 (m) to mean 'all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article.' Section 333 (a) makes the violation of any of the provisions of § 301 a misdemeanor.

"Four questions are argued for reversal of the judgment. In substance appellants' contentions are (1) the misbranding, if any, must occur in the labels used, and the labels must accompany the drug into interstate commerce; (2) the representations made in the labeling were honest expressions of their opinion; (3) the court erred in instructing the jury; and (4) the doctrine of *res judicata* was applicable.

"First: Appellants argue that the misbranding must occur in the labels used and the labels must accompany the drug into interstate commerce; that there is nothing in any of the three items of printed matter that informs the patient as to how the medicine is to be used; that the ingredients of the medicine are not given in the literature and no therapeutic claim is made for it, nor does any statement appear that it is efficacious in the treatment of diabetes except as to results had in prior cases.

"The record discloses that all three items of printed matter or literature are not involved in every count. The circular is involved in each count and is the only printed matter in counts 2, 5 and 7. In addition to the circular, counts 1, 3 and 4 involve the leaflet, and counts 4 and 6 involve the letter. The circumstances under which the drug and the literature were introduced or delivered for introduction into interstate commerce varied, but the general pattern was the same. A prospective patient, living outside of Indiana, addressed a letter of inquiry to appellants' clinic and in response received the printed circular and sometimes the form letter. The circular contained the following statements and representations.¹ The patient thereafter attended appellants' clinic, and while there received the leaflet containing diet recommendations which stated in part,² and in some instances also received a copy of the circular. Before leaving, the patient had delivered to him, or appellants later shipped to him, a supply of the drug constituting a three-months' treatment. In five of the seven counts (counts 1, 4, 5, 6 and 7) it was alleged that a supply of the drug, other than that received by the patient at the clinic, was shipped from the clinic to the patient. In those counts the shipment of the additional supply of the drug and the accompanying labeling is charged as the violative shipment.

"We have already been told that the phrase 'accompanying such article' is not restricted to labels that are on or in the article or package that is transported, and that the first clause of § 321 (m) clearly embraces advertising or descriptive matter that goes with the package in which the article is transported. The second clause—'accompanying such article'—has no specific reference to packages, containers or their contents, and it plainly includes what is contained within the package whether or not it is 'upon' the article or its wrapper or container, *Kordel v. United States*, decided by the United States Supreme Court on November 22, 1948, and the advertising matter need not travel with the drug, *United States v. Urbuteit*, decided by the United States Supreme Court on November 22, 1948. And since in our case it appears that the printed matter was used in the sale of the drug, that it advertised and explained the use of the drug, and that the drug and the printed matter moved from Indiana to a point outside of the State of Indiana, we are impelled to hold that the printed matter was 'labeling' within the meaning of the Act.

"Second: Appellants insist that the representations made in the labeling were expressions of opinion that they honestly believed. They assert that

¹ "3 Months' Medical Treatment to take home with you when you leave the institute * * *

"* * * there is real hope for the diabetic, and the possibility of recovery * * *
 "When this hope is presented in the form of a method and a treatment, which is free from prolonged or continuous dieting, with internal medicine taken by mouth, and without the necessity of absence from home, work, or business, it is certain to receive the most eager consideration of every diabetic. This consideration is invited in terms of what actually has been accomplished in a large number of cases of relief and recovery.
 * * *

"The Kaadt Diabetic Institute is the culmination of over thirty years of successful treatment of diabetics by Dr. C. F. Kaadt * * *

"The principal method of treatment is an internal medicine taken by mouth.
 * * *

"In the majority of cases the patient resumes a normal diet within two or three weeks after beginning the treatment.
 * * *

"The files of the Institute contain many letters from grateful and appreciative patients expressing their recovery and a return to normal living."

² "Accurate dosage is difficult so if you feel that you are not getting along as well as you should increase your dose a little. It may be necessary to double it. On the other hand, if you are taking too much decrease it a little, or put in more water. The amount of water can be decided by the patient as it causes no loss of effectiveness by diluting. Drink plenty of water."

'this is a repeat of the constant quarrel existing in the medical profession as to what is proper and what is improper treatment of disease'; that a difference of judgment among medical men as to the best course or method of treatment does not tend to prove that either party is wholly wrong or wholly right, and that all this case reflects is that certain physicians believe in one course of treatment and other physicians believe in another course of treatment. They make the point that before a court is warranted in submitting the false or misleading qualities of an assertion of effectiveness to a jury to decide, it must be satisfied that something more is involved than mere differences of opinion between schools or practitioners.

"In this case, the issue left to the jury was whether the labeling was false and misleading in that the statements in the printed matter represented and suggested and created in the mind of the reader and led him to believe that the drug was efficacious in the cure, mitigation, or treatment of diabetes. The labeling, as we have already observed, represented that 'there is *real* hope for the diabetic, and the possibility of recovery; * * * this hope is presented in the form of a method and a treatment, which is free from prolonged or continuous dieting * * *. This consideration is invited in terms of what actually had been accomplished in a large number of cases of relief and recovery. * * * In the majority of cases the patient resumes a normal diet within two or three weeks after beginning the treatment.'

"The drug or treatment consisted principally of a mixture of vinegar and potassium nitrate (saltpeter); Taka-diastase, a proprietary digestive preparation, was sometimes added, but analysis revealed no Taka-diastase because it is inactivated and destroyed in a solution as strongly acid as the vinegar medicine. To show the ineffectiveness of the treatment, there was the testimony of patients who had been treated at the clinic and who had subjected themselves to the recommended home treatment with the vinegar medicine, and the testimony of relatives of former patients who had undergone the treatment and subsequently died. Each of these histories was supported by competent medical testimony. A diabetic under competent medical care, taking insulin and on a regulated diet, with his disease under control, was induced to enter the clinic for the prescribed period. In accordance with appellants' recommendations, he decreased his dosage of insulin or discontinued it and substituted appellants' treatment. After subjecting himself to appellants' treatment, he experienced results that commonly follow uncontrolled or improperly treated diabetes. The serious and irreparable injuries that followed included diabetic coma, permanent eye injuries, and gangrene resulting in amputation.

"Outstanding medical authorities who were specialists in the treatment of diabetes, testified that the treatment used and recommended by appellants would have no effect in the treatment of diabetes; that it was worthless and absolutely of no value. These experts testified that the opinions expressed by them represented the consensus of medical opinion of the authorities on diabetes; that insulin was the only drug known to be effective in the treatment of diabetes; that a proper diet and exercise must be integrated with the dosage of insulin; and that the patient must be educated to look after his condition.

"We have already held that a consensus of medical opinion is a question of fact and provable as such, *United States v. Dr. David Roberts Veterinary Co.*, 104 F. 2d 785, and it has been held that a conflict of medical opinion concerning the effectiveness of a drug also presents a question of fact, *Seven*

Cases v. United States, 239 U. S. 510, and since it is not necessary in a prosecution under the Act to prove guilty knowledge or wrongful intent, *United States v. Dotterweich*, 320 U. S. 277; *United States v. Parfait Powder Puff Co.*, 163 F. 2d 1008; and *United States v. Greenbaum*, 138 F. 2d 437, we think the jury's finding that the labeling was false and misleading was supported by substantial evidence.

"Third: It is argued that under an instruction given the jury, the jury might return a verdict of guilty on all counts even though the unlawful distribution was entirely intrastate.

"In determining whether there is error in the court's instructions the charge must be viewed as a whole, *United States v. Carruthers*, 152 F. 2d 512; and *United States v. Fleener*, 162 F. 2d 935. The trial judge in the instant case, in an endeavor to guide the jury in its determination of whether any or all of the defendants shared the required responsibility in the conduct of the business, told the members of the jury that if they found that any or all of the defendants shared responsibility in conducting the business and that the operation of that business resulted in unlawful distribution of misbranded drugs, the defendants who shared such responsibility might be found guilty. He also instructed the jury that the burden of proof was upon the Government to prove every material allegation of the indictment and to establish the defendants guilty beyond a reasonable doubt, and that in determining whether the defendants did have a responsible share in the conduct of the business, it must take into consideration the work that each defendant did at the Kaadt Diabetic Clinic or Institute, the duties and responsibilities of each, and the extent to which each controlled or directed the conduct of the business.

"It is true, appellee did not show that in each instance all of the defendants physically participated in introducing the misbranded drug into interstate commerce. But physical participation is not necessary in order to have criminal responsibility attach for a violation of the Act. *United States v. Dotterweich*, *supra*, 284, 285, and *United States v. Parfait Powder Puff Co.*, *supra*.

"Appellants also complain of the form of the verdicts. It is claimed the court failed to instruct the jury that defendants could be found guilty on some counts and not guilty on others. And they complain of an instruction which told the jury that the Government need not prove that all of the statements in the labeling were false or misleading, and that if the jury found that any one of the claims or statements in the labeling was false or misleading it might find that the drugs in question were misbranded. The criticism heaped upon the instruction is that all three items of printed matter were not involved in each of the counts, and that in deliberating on a particular count, the jury might have considered items of printed matter not involved in that count. But the court also told the jury that it might consider each separate item, and in the counts where more than one piece of printed matter was involved, it might consider the effect of the combined influence of all types of printed matter involved.

"The record discloses that no objection was taken to the form of the verdicts or to the giving of this instruction. In this state of the record, under Rule 30 of the Federal Rules of Criminal Procedure, 18 U. S. C. A. foll. § 687, appellants are precluded from a review. We have, however, considered the points raised. We think the trial judge made it clear to the jury that each defendant could be found either guilty or not guilty on each of the counts, and that it was told that in weighing the evidence in a particular count it should consider only the

items of printed matter involved in that count. There was no error committed by the court in instructing the jury.

"Fourth: Appellant Charles F. Kaadt contends that the court erred in refusing to invoke the doctrine of *res judicata*.

"To be sure, the doctrine of *res judicata* is applicable to criminal as well as civil proceedings, and operates to conclude those matters in issue which have been determined by a previous verdict, even though the offenses be different. *Scalfon v. United States*, 332 U. S. 575. In our case it appears that during the trial Kaadt offered in evidence the verdict of a jury and the opinion of the District Court in 1940 in the case of the *United States v. Charles F. Kaadt*, 31 F. Supp. 546. The indictment in that case charged him with a scheme to defraud and the use of the mails to further such a scheme. He asserts that the question and issue passed upon in the prior action dealt with the therapeutic value of his medicine, and argues that that issue can not again be litigated in this case. He should not be vexed more than once for the same cause. In support of his argument he cites, among other cases, *United States v. Oppenheimer*, 242 U. S. 85; *Oklahoma v. Texas*, 256 U. S. 70; and *Tait v. Western Maryland Railway Co.*, 289 U. S. 620.

"Counsel for appellee concedes, as he must, the propriety of invoking *res judicata* when the issues have previously been tried and determined, but to avoid the application of the doctrine, he points to the fact that in a scheme to defraud the significant fact is the intent and purpose, and that the two essential elements of the offense of using the mails to defraud (18 U. S. C. A. § 338) are the existence of a scheme to defraud and the placing or causing to be placed in the post office a letter, post card, package, writing, circular, pamphlet, or advertisement, for the purpose of executing the scheme. *Fournier v. United States*, 58 F. 2d 3; *United States v. Lowe*, 115 F. 2d 596; and *United States v. Cohen*, 145 F. 2d 82.

"We agree with appellee that it is impossible from this record to ascertain on what ground the jury acquitted Kaadt of the offense of using the mails to defraud. But the instant prosecution does not involve any question of fraud. The misbranding charged is based on § 352 (a) of the Act which provides that a drug or device shall be deemed to be misbranded if its labeling is false or misleading in any particular. And *Sealfon v. United States*, *supra*, is of no aid to appellant for the reason that in the unique circumstances of that case, the jury's verdict in the conspiracy trial was a determination favorable to Sealfon of the facts essential to a conviction of the substantive offense. Appellee in the present case was not required to prove intent to defraud. Thus the offense of using the mails to defraud and the offense of introducing or delivering for introduction into interstate commerce misbranded drugs are not the same, and hence there is no *res judicata*. Compare *United States v. Five cases*, 156 F. 2d 493.

"The judgment of the District Court is affirmed."

2579. Misbranding of Adolphus vitamin and mineral products. U. S. v. Adolphus Hohensee. Plea of not guilty. Tried to the jury. Verdict of not guilty on count 1; verdict of guilty on remaining counts. Fine \$1,800. (F. D. C. No. 20125. Sample Nos. 31973-H to 31983-H, incl.)

INFORMATION FILED: September 25, 1946, District of Arizona, against Adolphus Hohensee, of Scranton, Pa., and Phoenix, Ariz.

ALLEGED SHIPMENT: On or about April 2, 1945, from the State of Arizona into the State of California.